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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,455	02/21/2002	James C. Paulson	019957-011212US	3039

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EXAMINER	
RAO, MANJUNATH N	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,455	PAULSON ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *60-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 60-83 are now pending in this application.

Claims 60-83 are now subjected to a new round of restriction. This is because, Examiner has come to realize that applicants are claiming methods which uses different enzymes leading to formation of different products, even though it is broadly called as method of sialylating. According to applicant's own admission in the response to the previous Office action as well as in the specification, these claims are directed to "processes which recite the use of particular enzymes". Furthermore, applicant admits in the specification that the nomenclature of the enzymes used in the processes is based on the reference of Tsuji et al. (Glycobiology, 1996, Vol. 6(7):v-xiv). A perusal of the above reference indicates that the sialyltransferase enzymes come in different kinds even when broadly classified as ST6 or ST3. Therefore, instant claims are directed to different methods and hence a new restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 60-62, 81-83, drawn to a method of sialylating a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Photobacterium sp.* 2,6-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic

acid from said sialic acid donor moiety to said saccharide group, classified in class 435, subclass 97.

II. Claims 60, 63-64, 81-83 drawn to a method of sialylating a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Neisseria sp* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, classified in class 435, subclass 97.

III. Claims 60, 65-66, 81-83, drawn to a method of sialylating a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Campylobacter jejuni.* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, classified in class 435, subclass 97.

IV. Claims 60, 67-68, 81-83, drawn to a commercial-scale production method of sialylating a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Haemophilus sp.* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, classified in class 435, subclass 97.

V. Claims 69-72, 73-74, 81-83, drawn to a method of *in vitro* sialylation of a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Neisseria sp* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, wherein the enzyme used is up to 50 mU/mg of glycoprotein and wherein the method yields a glycoprotein having sialylation of at least about 80% of terminal galactose residues present on the saccharide groups, classified in class 435, subclass 97.

VI. Claims 69-72, 75-76, 81-83, drawn to a method of *in vitro* sialylation of a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide

group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Photobacterium sp.* 2,6-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, wherein the enzyme used is up to 50 mU/mg of glycoprotein and wherein the method yields a glycoprotein having sialylation of at least about 80% of terminal galactose residues present on the saccharide groups, classified in class 435, subclass 97.

VII. Claims 69-72, 75-76, 81-83, drawn to a method of *in vitro* sialylation of a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Campylobacter jejuni.* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, wherein the enzyme used is up to 50 mU/mg of glycoprotein and wherein the method yields a glycoprotein having sialylation of at least about 80% of terminal galactose residues present on the saccharide groups, classified in class 435, subclass 97.

VIII. Claims 69-72, 75-76, 81-83, drawn to a method of *in vitro* sialylation of a saccharide group on a recombinant glycoprotein, the method comprising contacting a saccharide

group which comprises a galactose or N-acetylgalactosamine acceptor moiety on a recombinant glycoprotein with a sialic acid donor moiety and a recombinant sialyltransferase of a bacterial origin (*Haemophilus sp.* 2, 3-ST) in a reaction mixture which provides reactants required for sialyltransferase activity for a sufficient time and under appropriate conditions to transfer sialic acid from said sialic acid donor moiety to said saccharide group, wherein the enzyme used is up to 50 mU/mg of glycoprotein and wherein the method yields a glycoprotein having sialylation of at least about 80% of terminal galactose residues present on the saccharide groups, classified in class 435, subclass 97.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VIII are patentably distinct from each other. The method of sialylating a saccharide group in these 8 methods are all unrelated as they comprise distinct steps, utilize different enzymes (2,3-ST or 2,6-ST) substrates (donors and acceptors) and produce different results (i.e., products with specific linkages). They are subject to separate manufacture and sale and have acquired separate status in the art and separate fields of search.

Examiner has restricted even between the bacterial 2,3-ST enzymes because the reference of Tsuji et al. lists four different ST3 enzymes with its own unique acceptor molecules. It is not clear to the Examiner whether all the bacterial 2,3-STs have identical function or belong to one of the four different class of ST3 enzymes.

In response to the previous restriction, applicants have argued restriction discretionary and that it is made to avoid placing an undue burden on the Examiner and that above claims do not place such an undue burden on the Examiner. Examiner respectfully disagrees with such an

argument. Examiner has made all attempts to keeps most claims together taking on the burden of the searches, but he cannot combine all the above claims in a single group unless applicants submit that these inventions are obvious variation of a single invention.

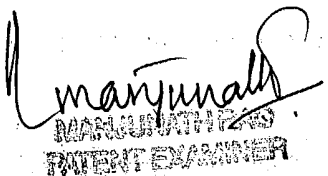
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization

where this application or proceeding is assigned is 703-872-9306 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao
June 15, 2004